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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,964	07/17/2003	John Nicholas Staniforth	478.1063	2030

7590 06/10/2009

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
06/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,964	STANIFORTH ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,24,30-38,47-51,69,70 and 72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,24,30-38,47-51,69,70 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed March 9, 2009 have been entered.

Claims 1-17, 24, 30-38, 47-51, 69-70, and 72 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 24, 30-38, 47-51, 69-70, and 72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 9, 15, 16, 98-100, and 126 of copending Application No. 10/413,022 ('022) in view of US 5,476,093 ('093). Although the conflicting claims are not identical, they are not patentably distinct from each other because '022 teaches the method of

treating sexual dysfunction by inhaling apomorphine in the dosage and particle size herein claimed.

'022 does not expressly teach the use of dry powder inhaler with the herein claimed formulation that possess the herein recited characteristics.

'093 teaches a dry powder inhaler device that meets the herein claimed characteristics (See Fig. 3a for example).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ the herein claimed inhaler with the herein claimed components in the '022's method of treating sexual dysfunction.

One of ordinary skill in the art would have been motivated to employ the herein claimed inhaler with the herein claimed components in the '022's method of treating sexual dysfunction as these agents and the use of dry powder inhaler are well-known in the inhalation medical technologies, and thus clearly within the purview of skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's remarks with regard to the outstanding double patenting rejection filed March 9, 2009 are acknowledged. In the mean time, the double patenting rejection remains.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17, 24, 30-38, 47-51, 69-70, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0006933 ('933) in view of US 5,699,789 ('789), Ensuring Patient Care, 2nd ed., 1999, pages 15-21, US 5,476,093 ('093), Lucas et al., (Pharmaceutical Research, 1999;16(10):1643-1647).

'933 teaches a method of treating female sexual dysfunction and male erectile dysfunction by employing inhalation apomorphine (See paragraph 0031 – 0035, also claims 6-7 and 12-16). '933 teaches the human sexual dysfunction and treatment thereof (See paragraph [0002] to [0010]). '933 also teaches 025-5ng/ml plasma

concentration of apomorphine with much less side effects such as emesis and at the same time, useful in treating sexual dysfunction (See paragraph [0023] and [0073]). '933 also teaches that the side effect versus Cmax can be optimized based on the data of the studies disclosed in the specification (See for example, paragraph [0071] last sentence and paragraph [0073] last sentence). '933 also teaches the employment of adjunct agents such lactose (See paragraph 0055). '933 also teaches dry powder inhaler can be employed (See claim 7).

'933 does not expressly teach the dose of apomorphine. '933 does not expressly teach the particle size of the apomorphine. '933 does not expressly teach the use of the herein claimed force additives such as leucine. '933 does not expressly teach the use of a dry powder inhaler device possessing the herein claimed characteristics.

'789 teaches the desirable particle size for inhalation delivery of drugs as 0.5-5 microns (see col. 2, line 4).

Ensuring Patient Care teaches also teaches the optimal particle size for the active as no more than 5-10 μm (See page 19, col. 2, fourth paragraph).

'093 teaches a dry powder inhaler device that meets the herein claimed characteristics (See Fig. 3a for example).

Lucas et al. teaches that leucine enhances the flow properties of the powders and improves the emptying of the device (See for example page 1646, col. 2).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ the herein recited particle size and dosage of apomorphine in a method of treating sexual dysfunction. It would have been obvious to one of ordinary

skill in the art at the time of invention to employ the herein claimed ingredients into the inhalation formulation of apomorphine to treat sexual dysfunction.

One of ordinary skill in the art would have been motivated to employ the herein recited particle size and dosage of apomorphine in a method of treating sexual dysfunction. The optimal particle size for dry powder inhalation is known. Formulating apomorphine into such particle size would be reasonably expected to be effectively deliver apomorphine into the lung of the patients. Therefore, the optimization of dosage range to herein claimed in order to achieve the optimal therapeutic plasma level of apomorphine is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have been motivated to employ the herein claimed ingredients into the inhalation formulation of apomorphine to treat sexual dysfunction because leucine can improve the properties of the dry powder formulation and III) the dry powder inhalation device for delivering the drug is also known in the art. Therefore, employing these well-known agents and device for inhalation delivery of apomorphine to treat sexual dysfunction is considered obvious as being within the purview of the skilled artisan.

Response to Arguments

Applicant's arguments filed March 9, 2009 averring the Gupta's use instillation for inhalation model as not predictable and inaccurate have been fully considered but they are not persuasive. The examiner notes that it is clear the Gupta has already envisioned the inhalation route of administration using dry powders. Even though if the dosage or

pharmacokinetics taught in Gupta are not as accurate, one of ordinary skill in the art would still need to perform routine experimentation to find out the safe and effective dosage of apomorphine for the treatment of erectile dysfunction (ED). Furthermore, the applicant argues that Gupta is using solution and such that the herein claimed onset of action would not be able to achieve. The examiner notes that Gupta has envisioned the powder inhalation as one of the delivering method of apomorphine for treating sexual dysfunction. It would be within the purview of the one of ordinary skill in the art to determine the optimum way to deliver apomorphine in the method of treating erectile dysfunction.

Applicant's arguments filed March 9, 2009 averring the use of powdered low-dose apomorphine to treat sexual dysfunction would have no side effect have been considered, but are found not persuasive. The examiner notes that with the guidance provided in Gupta, one of skilled artisan would adjust the dosage and the route of administration so that the serum concentration of apomorphine would be within the range of 0.25 – 5ng/ml, absent evidence to the contrary.

Applicant's arguments filed March 9, 2009 averring by considering the teachings of Gupta, one of ordinary skill in the art would rather consider other route of administration have been considered, but are not found persuasive. In view of the teachings of Gupta, one of ordinary skill in the art would adjust the dosage and the route of administration so that the serum concentration of apomorphine would be within the range of 0.25 – 5ng/ml. The examiner notes that "All the disclosures in a reference must be evaluated.., a reference is not limited to the disclosure of specific working

examples." *In re Mills*, 470 F.2d 649, 651, 176 USPQ 196, 198 (CCPA 1972). Since the teachings of Gupta are not merely limited to the examples therein, possessing the teachings of the cited prior art as a whole, one of ordinary skill in the art would adjust the dosage and route of administration to that of instant claims, absent evidence to the contrary.

In response to the citing of Appeal No. 2007-4423, Decision of Appeal dated July 23, 2008, the examiner notes that there is reason to modify the known composition in a way that result in the claimed composition. Such reason resides on the fact that the target serum concentration of apomorphine is in the range of 0.25 – 5ng/ml. When the serum concentration within such range is achieved, the side effect is minimum. Therefore, possessing the teachings of the cited prior art (especially in view of the route of administration and formulation might change the pharmacokinetics), one of ordinary skill in the art would have been reasonably expected to employ the herein claimed dosage and route of administration of apomorphine to treat sexual dysfunction.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

/San-ming Hui/

Primary Examiner, Art Unit 1617